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Wuxi Jiajian Medical Instrument Co., Ltd
Qinghong Rd., Ehu Town, Xishan District, Wuxi, China
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JIAJIAN®

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K112288
Date:	March 15th, 2012
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd Qinghong Rd., Ehu Town, Xishan District, Wuxi, China 214116
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add.: Room 1706 Yuesha, No. 128 Songle Rd., Songjiang, Shanghai, China 201600 E-mail: doris_d@126.com Tel: 86 21-31261348 Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Jiajian® TENS
Common Name:	TENS (Transcutaneous Electrical Nerve Stimulator)
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	882.5890
Product Code:	GZJ
Device Class:	II
Review Panel:	Neurology
Device Description:	Jiajian® TENS, is Transcutaneous Electrical Nerve Stimulator for pain relief. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. It is a battery-powered portable device, comprising electronic stimulatory module and accessories of lead wires and 9 volt type 6F22 battery. When using this device, the physician should select and use 510(k) cleared electrodes. The area of electrodes must be larger than $8cm^2$. The electronic stimulatory module has the operating elements of ① Display screen, ② Menu keys, ③ Modification keys, ④ On/Off key, ⑤ Battery compartment and ⑥ Outlet socket. The display screen can show (a) battery power, (b) selected program, (c) lasting time or left time of a program, (d) current intensity for each channel, (e) program phase and (f) locking state. The menu key "P" is for selecting standard program or user-program, and for locking; the menu key "E" is for editing program when the device is not being locked. The modification key "3A" and "3B" are for intensity level adjustment during stimulation. The outlet socket is used to connect skin electrodes by lead wires.

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The device has 12 selectable programs, which can be grouped into 4 output modes, i.e. Normal mode (P1, P2, P3, P4, P5, P6), Burst mode (P7, P12), Rate & width modulation (P8), and Intensity modulation (P9, P10, P11).

Indications for use: Jiajian® TENS is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.

3. Substantial Equivalence to Predicate device:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

Parameters		**New Device**	**Predicate Device**
1.	510(k) Number:	K112288	K071951
2.	Device Name	Jiajian® TENS	TENS, Model EV-804
3.	Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	Everyway Medical Instruments Co., Ltd
4.	Accessories	Electrode cables and batteries	Electrodes, gel, electrode cables and batteries
5.	Intended use	For symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.	For symptomatic relief and management of chronic intractable pain, adjunctive treatment in the management of post surgical and post traumatic pain
6.	Power Source(s)	9V Battery type 6F22	9V Battery type 6F22
	- Method of Line Current Isolation	N/A	N/A
	- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- 2μA N/A	-- N/A N/A
7.	Average DC current through electrodes when device is on but no pulses are being applied (μA)	< 0.01μA	< 0.01μA
8.	Number of Output Modes	4	5
9.	Number of Output channels:	2	2
	- Synchronous or Alternating?	Synchronous	Synchronous
	- Method of Channel Isolation	By Transformer	By Transformer
10.	Regulated Current or Regulated Voltage?	Voltage control	Voltage control
11.	Software/Firmware/Microprocessor Control?	Yes	Yes
12.	Automatic Overload Trip?	No	No
13.	Automatic No-Load Trip?	No	No
14.	Automatic Shut Off?	Yes	No
15.	User Override Control?	No	No

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16.	Indicator Display:	On/Off Status?	Yes	Yes
		Low Battery?	Yes	Yes
		Voltage/Current Level?	Yes	Yes
17.	Timer Range (minutes)		30 min or 1~99 min	5~60min or continuous, 5 min/step
18.	Compliance with Voluntary Standards?		IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2
19.	Compliance with 21 CFR 8988?		Yes	Yes
20.	Weight (grams)		170g without battery	115g (battery included)
21.	Dimensions (mm) [W x H x D]		114*59*27 mm	101*61*24.5mm
22.	Housing Materials & Construction		ABS; Injection molded	ABS; Injection molded
23.	Waveform		Monophasic	Asymmetrical biphasic
24.	Shape		Rectangular pulse	Rectangular pulse
25.	Maximum Output Voltage (volts)		36V @500Ω	50 V @500Ω
26.	Maximum Output Current (specify units)		72mA @500Ω	100mA @500Ω
27.	Pulse Duration (μsec)		The range of Pulse width control is between 60μS and 300μS.	The range of Pulse width control is between 50μS and 300μS.
28.	Frequency (Hz) [or Rate (pps)]		The range of Pulse rate control is between 0.5Hz and 120 Hz.	The range of Pulse rate control is between 2Hz and 150 Hz.
29.	Net Charge (μC per pulse)		0.7776μC @500Ω	0.945μC @500Ω
30.	Maximum Phase Charge, (μC)		21.6μC @500Ω	30μC @500Ω
31.	Maximum Average Current, (mA)		2.592mA @500Ω	4.5 mA @500Ω
32.	Maximum Current Density, (mA/cm², r.m.s.)		1.71mA/cm² @500Ω	1.33mA/cm² @500Ω
33.	Maximum Average Power Density, (W/cm²)		11.73mW/ cm² @500Ω	3.7mW/ cm² @500Ω

Substantial Equivalence Discussion:

Similarities between New device and Predicate Device:	intended use, power supply, output modes, output channels, pulse width control, pulse rate control, with microprocessor control, testing standards
Differences between New device and Predicate Device:	weight, dimensions, waveform, output voltage and current, net charge
Conclusion:	The maximum output voltage, maximum output current, and maximum phase charge of the new device are smaller than the predicate device. The maximum current density and maximum average power density are larger than the predicate device, but the values conform to the safety requirements of FDA regulation. In all important respects, the Jiajian® TENS are substantially equivalent to the TENS EV-804 (K071951). This conclusion is based upon comparison on design, technical characteristics, output mode, intended use, and safety standards complied with. Any differences in the technological characteristics do not raise any new safety and effectiveness issues.

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4. Safety and Effectiveness of the device:

Jiajian® TENS is safe and effective as the predicate devices cited above.

The new device has passed testing according to the safety standards:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;

* IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators; and

* IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

The conclusion drawn from the safety testing is that the new device is substantially equivalent to the predicate device. Furthermore, the new device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Wuxi Jiajian Medical Instrument Co., Ltd
c/o Ms. Doris Dong
Shanghai CV Technology Co., Ltd
Room 1706, No. 128 Songle Rd., Songjiang Area
Shanghai, China 201600

Re: K112288
Trade/Device Name: Jiajian® TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: Not Dated
Received: April 17, 2012

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K 112288

Device Name: Jiajian® TENS

Indications for Use: Jiajian® TENS is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112288